UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,972	08/29/2001	Yoshihide Murakami	213338	7743

23460 7590 08/16/2004

LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6780

EXAMINER	
REDDICK, MARIE L	

ART UNIT	PAPER NUMBER
1713	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/941,972	MURAKAMI ET AL.	
	Examiner	Art Unit	
	Judy M.\Reddick	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see the paper, filed 07/26/04, with respect to the rejection(s)of claim(s) 1-16 under 35 USC 102(b/e)/103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Otsuka et al(U.S. 4,608,249) and the claims of U.S. Copending Application 10/317,076. Therefore, prosecution on the merits is herein reopened. The New Grounds of Rejection are set forth below.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1 & 9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Otsuka et al(U.S. 4,608,249).

> As to claims 1 and 9, Otsuka et al teach a hydrophilic therapeutic material comprising a carrier and a drug-containing patching layer wherein, said patching layer comprises i) a copolymer of 5 to 75 % by weight of a (meth)acrylic ester having an ether group in the molecule, 85 to 15 % by weight of an alkyl (meth)acrylate and 10 to 50 % by weight of a polar monomer which includes functional monomers such as (meth)acrylic acid, ii)0.5 to

20 parts by weight per 100 parts by weight of the copolymer of an adjuvant which includes diisopropyl adipate, diethyl sebacate, ethyl laurate, etc.(the Abstract, col. 1, lines 5-9 & 43-68, col. 2, lines 4-63, col. 3, lines 5-45, the Runs, especially Run 3 and the claims of Otsuka et al). Otsuka et al therefore anticipate the instantly claimed invention. Specifically, one would have readily envisaged the use of lower amounts of acrylic acid in Run 3, viz., 10 parts, following the guidelines of Otsuka et al @ col. 1, line 67 and col. 2, line 63.

As to the gel fraction limitation, as claimed, it would be expected that this property would be inherent in the acrylic copolymer of Otsuka et al since the acrylic copolymer of Otsuka et al is essentially the same as the claimed acrylic copolymer and in the absence of the USPTO to have at its disposal the tools and facilities deemed necessary to make physical determinations of this sort.

It has been held that where applicants claims a composition in terms of function, property of characteristic where said function is not explicitly shown by the reference and where the Examiner has explained why the function, property or characteristics is considered inherent in the prior art, it it is appropriate for the Examiner to make a rejection under both the applicable sections of 35 USC 102 and 35 USC 103 such that the burden is placed upon applicant to provide clear evidence that the respective compositions do, in fact, differ as provided for under the guise of In re Best, 195 USPQ 430, 433(CCPA 1977); In re Fitzgerald et al, 205 USPQ 594.

Even if it turns out that the claims are not anticipated by teachings of Otsuka et al, it would have been obvious to the skilled artisan to extrapolate, from Otsuka et al, the adhesive composition, as claimed, as per such having been within the purview of the general disclosure of Otsuka et al and with a reasonable expectation of success.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 2-8 and 10-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Otsuka et al(U.S. 4,608,249) in combination with Muraoka et al(U.S. 5,876,745) or Muraoka et al(U.S. 6,139,867).

The disclosure of Otsuka et al is relied on for all that it teaches as set forth in the Grounds of Rejection supra as applied to claims 1 & 9. Further, the disclosure of Otsuka et al differs basically from the claimed invention as per the non-express disclosure of an embodiment directed to the specific carboxylic acid ester(2-6 and 10-14) and a crosslinking agent(7, 8, 15 and 16).

However, each of Muraoka et al teach a drug-incorporated, pressure-sensitive adhesive layer, similar to that of Otsuka et al, comprising an acrylic copolymer and an organic

liquid, having been subjected to crosslinking, in order to increase cohesiveness providing a feeling of softness and moderate adhesion when applied to the skin, using, as a crosslinking agent, a polyisocyanate compound, an organic peroxide, etc. (the Abstract and cols. 2-5 of Muraoka et al '745 and Muraoka et al '867).

It would have been obvious to the skilled artisan to i) swap the carboxylic acid ester compounds of Otsuka et al for the glycerol esters of either of Muraoka et al, based on their identified scope equivalency, and with a reasonable expectation of equivalent results and ii) to use a crosslinking agent, as identified in either of Muraoka et al, in the system of Otsuka et al and with a reasonable expectation of enhancing the properties of the drug-containing patching layer of patentee. Criticality for such, commensurate in scope with the claims, not having been demonstrated on this record.

While the glycerol esters of each of Muraoka et al are generic to the claimed carboxylic acid ester, such is a necessary implication that any glycerol ester, including the claimed glycerol esters, would have been operable within the scope of patentees' invention and with a reasonable expectation of success.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 11, 13 & 14 are of copending Application No. 10/317,076. Although the conflicting claims are not identical, they are not patentably distinct from each other because the adhesive layer mainly comprised of an acrylic polymer, a

component compatible with the acrylic polymer and liquid or pasty at ordinary temperature which includes a carboxylic acid ester such as glyceryl monocaprylate, glyceryl tricaprylate, glyceryl trilaurate, glyceryl triisostearate and glyceryl trioleate and a chemical crosslinking agent such as an isocyanate compound and an organic peroxide per the claims of copending application '076 overlaps in scope with the adhesive composition for application to skin which comprises an acrylic copolymer(100 parts by weight) obtained from a monomer mixture comprising a (meth)acrylic acid alkyl ester monomer(40 to 80 wt %), an alkoxy group-containing ethylenically unsaturated monomer(10 to 60 wt %) and a carboxy group-containing ethylenically unsaturated monomer(1 to 10 wt %), a carboxylic acid ester(20 to 120 parts by weight) which is liquid or paste at room temperature, wherein the acrylic copolymer has a gel fraction of 30 to 80 wt % per the instantly claimed invention with the understanding that the acrylic copolymer of copending application '076 meets the acrylic copolymer of the instantly claimed invention as expressly taught at pages 10 and 11. Furthermore, the contents of the acrylic copolymer and the monomer components making up the acrylic copolymer are generic and therefore necessarily imply that any content, including the claimed contents, would have been operable within the scope of the claimed invention. As to the gel content, such would be considered to be an inherent property of the acrylic copolymer of the claims of copending '076, as modified or not to involve anything unobvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy M. Reddick whose telephone number is (571)272-1110. The examiner can normally be reached on Monday-Friday, 6:30 a.m.-3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571)272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Judy M. Reddick
Primary Examiner
Art Unit 1713

JMR
08/12/04